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## EUROPEAN PATENT APPLICATION

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### ㉚ Compression device.

㉛ A pressure generating device for applying compressive pressures against a patient's limb through means of a flexible, pressurizable sleeve which encloses the limb having a means for automatically adjusting pressure within the sleeve to maintain a preselected pressure applied to the limb. The device has a pressure transducer and a controller which generates electrical signals in response to signals from the transducer that operate a flow control valve to control the flow of fluid to the pressure chamber of the sleeve.

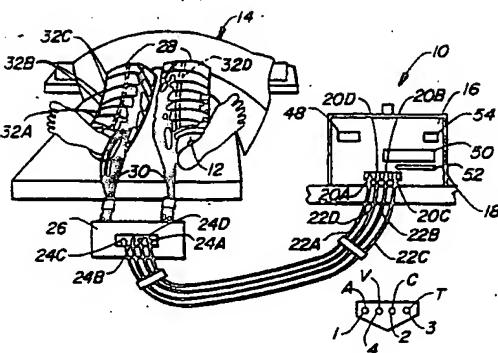


FIG. 1

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## BACKGROUND OF THE INVENTION

The present invention relates to a device for applying compressive pressures against a patient's limb through means of a compression sleeve enclosing the limb, and more particularly, to a means for automatically adjusting the pressure within the sleeve to maintain a preselected pressure.

Compression sleeves and devices for controlling them are well known and illustrated in the prior art in such patents as U.S. Patent Nos. 4,013,069 of Hasty; 4,030,488 of Hasty; 4,091,804 of Hasty; 4,029,087 of Dye et al; 3,942,518 of Tenteris et al; and 2,145,932 of Israel, and reference may be had thereto for general background information on structure and utility.

Flexible compressive sleeves having a plurality of pressure compartments/chambers are wrapped around the limb of a patient and are then pressurized to apply compressive pressure to different parts of the limb. The sleeves are connected to a source of pressurized fluid which is regulated by a controller. The controllers generally operate to form pressure cycles which propel the blood upwards from the ankle towards the thigh.

Such devices can be misadjusted or drift from proper adjustment so that safe and effective pressure may not be applied to the limbs.

Prior art such as U.S. Patent No. 4,396,010 of Arkans, U.S. Patent No. 4,702,232 of Gardner and U.S. Patent No. 4,013,069 of Hasty, incorporated herein by reference, manually control the amount of pressure that is to be supplied to a patient's limb. Furthermore, although Arkans provides a method of depressurizing a pressure compartment by use of a pressure release device, Arkans' method of controlling the pressure applied to the limb is still provided by a manual control.

Even though the prior art has accomplished the depressurizing of chambers to reduce injury to a patient's limb, the pressure supplied to the pressure compartments is still manually controlled. Thus, a nurse must remain with the unit constantly until the pressure has come up to a preselected value and then they must frequently check and recheck the pressure unit to make sure the pressure setting remains steady. Additionally, changes in the patient's position may cause changes in the effective volumes of the pressure chambers resulting in undesirable changes in the pressures in the individual pressure chambers which requires further manual adjustment.

Applicant is not aware of any prior art that discloses or suggests that pressure applied to a patient's limb may be controlled by an automatic means.

Thus, a need exists for automatic control over application of pressure to the pressure chambers

so that a preselected pressure value is maintained, and the time required by a person to watch over a pressure monitor is further reduced. The present invention provides such an automatic control means to control pressure exerted on a patient's limb.

## SUMMARY OF THE INVENTION

The object of the present invention is to provide a pressure generating device for applying compressive forces against a patient's limb through a flexible pressurizable sleeve which encloses the limb having a means for automatically adjusting pressure supplied to the pressurized sleeve to maintain a preselected pressure value.

The device has a pressure transducer and a controller which generates electrical signals in response to signals from the transducer which operate a flow control valve that controls the flow of fluid to a solenoid controlled valve to automatically adjust the pressure in the sleeve.

Another object is to provide automatic pressure adjustment to eliminate the need for a nurse or similar person from having to continuously monitor the pressure selection to insure it remains at a preselected pressure value.

Another object of the present invention is to provide automatic pressure adjustment in response to changes in the effective volumes of the pressure chambers of the sleeve caused by changes in a patient's position.

Other objects will become more apparent from the following description of the preferred embodiment and claims.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the sequential compressive device as being used to apply compressive forces to the legs of a patient;  
FIG. 2 is a schematic diagram, partially in block form, showing the preferred embodiment;  
FIG. 3 is a timing diagram of the pressure cycles;  
FIG. 4 illustrates the flow control valve used to control the flow of fluid to solenoid valves; and  
FIG. 5 is a flow vs. plunger position chart.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1 and to briefly describe the compressive device, the compression device 10 is seen as supplying sequential compressive pressures and cooling to legs 12 of a patient 14. The device 10 includes a pressure controller 16 mounted in a case 18. The controller 16, generates

controlled pressures timed as illustrated in FIG. 3, at output ports 20A, 20B, 20C and 20D, respectively as will be described in detail hereinafter. The output ports 20A-20D are connected through flexible tubes 22A, 22B, 22C and 22D and are in fluid communication with input ports 24A, 24B, 24C and 24D of a manifold 26. Two sets of input ports are connected to a pair of compression sleeves 28 by a pair of flexible sets of tubes 30.

The compression sleeves 28 are identical to each other. And as shown in FIG. 1 each is wrapped around one of the patient's legs 12. Each sleeve has an ankle chamber 32A, a calf chamber 32B and a thigh chamber 32C. In addition, each sleeve has one or more ventilation chambers 32D for ventilating the patient's legs 12.

The sequential compression device described above is per se old and is shown, for example, in U.S. Patent No. 4,396,010 of Arkansas, and other patents referenced therein.

Referring to FIG. 2, the pressure generator 16 functions to repetitively generate pressure pulses to its output ports 20A-20D in the time sequence shown by wave-forms of FIG. 3. As seen by FIG. 3, the pressure cycles commence at time TA when pressure pulse A is applied to port 20A and the ankle chambers 32A are pressurized. At time TB, pressure pulse B is applied to port 20B and the calf chambers 32B are pressurized. At time TC, pressure pulse C is applied to port 20C and the thigh chambers 32C are pressurized. At time TD, pressure pulses A, B and C are terminated, chambers 32A, 32B and 32C are vented to the atmosphere, and cooling pulse D is applied to port 20D and ventilation chambers 32D. At the end of the cooling pulse, the entire sequence is repeated commencing with pressure pulse A.

Referring to FIG. 2, the pressure controller 16 has a compressor 74 as a generating source of pressurized fluid. In the preferred form of the invention, the pressurized fluid is air generated by an air compressor 74. The compressor 74 is connected through a conduit 70 to fluid junction 90 which is connected to solenoid valve 46D and the inlet opening 110 of flow control valve 44 through conduit 61. The discharge opening 120 of flow control valve 44 is connected through conduit 64 to the solenoid valve manifold 94. The solenoid valves 46A, 46B, 46C and 46D control the input of pressure through conduits 66A, 66B, 66C and 66D to a manifold 62 which has output ports 20A, 20D, 20B and 20C. The pressure transducer 34, of a commercially available type, is in fluid communication with the solenoid manifold 94 through pneumatic connection 68 and fluid junction 96.

The pressure transducer 34 senses the pressure at output port 20A through conduits 66A and 68; and then converts the pressure sensed into a

first electrical signal. The first electrical signal is an analog electrical signal and is communicated to a signal converter 36 through lead 78. This first electrical signal is received by the signal converter 36, of a per se known and commercially available type, which converts the analog electrical signal to a digital electrical signal. The digital electrical signal generated by the signal converter 36 is then communicated to a microprocessor 38 through lead 76. The digital signal is received by the microprocessor 38, also of a per se known and commercially available type; which is programmed to monitor and to compare the digital signal to a preselected pressure value. If there is a difference between the pressure sensed by the transducer 34 and the preselected pressure value, the microprocessor 38 then sends a second electrical signal to a driver circuit 40, of a commercially available type, through lead 76 which in turn sends pulses of current through lead 72 to a motor 42. The motor 42 preferably is a linear stepper motor that is commercially available, and operates the flow control valve 44 which controls the flow of fluid to solenoid valves 46A, 46B and 46C. Thus, the pressure applied to outlet ports 20A-C through solenoid valves 46A-C is dynamically regulated by automatic adjustment of the flow of pressurized fluid through flow control valve 44.

Referring to FIG. 4, a flow control valve 44 for controlling and automatically adjusting pressure in pressure sleeves is depicted. The valve has a hollow body member 100 which has an inlet opening 110 within which a precision orifice 112 is situated and a discharge opening 120. The body member 100 also has a chamber 130 in communication with the inlet and discharge openings. The chamber 130 has a cylindrical central portion 132. The body member 100 may be made from any type of material such as aluminum, steel, brass, etc., although the preferred material is plastic. The flow valve also has a means for sealing against fluid flow entering the chamber 130, the means including a plunger member 140 having a tapered pin 141 at its leading or distal end for releasably seating into the precision orifice 112 situated within inlet opening 110. The plunger 140 may be made of various materials, such as brass, steel, aluminum, other metals or composites, brass being preferred. Plunger 140 has a trailing or proximal sealing portion 142 in slideable fluid-tight contact with the walls of chamber 130 defining cylindrical portion 132. The taper of the tapered pin 141 preferably is a compound taper which permits plunger 140 to precisely control the flow of fluid through orifice 112. Attached to the hollow body 100 is a means for moving plunger 140. This means is a linear stepper motor 42. The plunger 140 is connected to a shaft 152 of the motor 42.

which extends into the hollow body 100. The motor moves the plunger 140 in a linear motion in and out of the orifice 112. The stepper motor 42 provides linear motion in increments of 0.002 (2 thousandths of an inch.) In addition, the motor 42 has a predetermined internal stop (not shown) to prevent the plunger 140 from jamming into the body of the motor. There is also a predetermined internal stop (not shown) to prevent the tapered pin 141 from jamming into the orifice 112. Because the stepper motor 42 is calibrated to move in increments of 2 thousandths of an inch it can move pin 141 precisely into and out of the orifice 112 without causing it to jam. Furthermore, because the pin 141 has a compound taper, the flow of fluid through orifice 112 can be precisely controlled, thereby providing finite adjustments in the flow of fluid to the solenoid valves and therefore to the compression chambers.

The flow is precisely controlled due to the combination of the incremental movement of plunger 140 and the compound taper of pin 141. As pin 141 is being moved into position for seating in the inlet opening 110 the compound tapered member reduces the area around the inlet opening 110 incrementally until it eventually seats in the orifice 112. This combination permits the finite pressure adjustments. As the tapered member is moved in and out of the inlet opening the area between the taper and the inlet opening diminishes or expands, thus, exact control over the pressure is had, which is necessary to maintain a preselected pressure. This control is illustrated in FIG. 5 wherein a comparison is made of the present invention compound taper and a standard plunger commonly used within flow control valves. The difference in the slopes of pressure is quite obvious. The slope of the pressure when using the standard plunger dips downward showing a drop in fluid flow has occurred. On the other hand the pressure slope of the present invention is stable and has no substantial pressure drops in its slope. This is important when providing pressure to a pressure sleeve that is being used on the limb's of a patient because any drop in pressure may cause the compressor supplying the pressure to over compensate and provide too much pressure which may possibly cause injury to the patient. By using this new valve there are no pressure drops, thus when automatically adjusting the pressure in the sleeves, an even flow of pressure will be assured and the compressor will not provide unneeded pressure to the sleeves.

It is unknown in the art to use a linear stepper motor to move a tapered member (plunger) in a linear motion in such a precise manner. Prior art motors were of the constant rotary motion type and would turn the plunger down and up by screwing it

into position. This has its disadvantages because if the rotary movement of the motor is not controlled, the rotary motion would exert a substantial force between the inlet and the plunger when seating the plunger so as to cause it to jam and not permit the plunger to be retracted. Although the rotary motion or movement of a rotary motor may be controlled, the cost to do so is prohibitive and thus, economically unsound for use in this art.

Referring once again to FIG. 1, the generator 16 is mounted to a case 18, the case in its preferred form being shown to have various controls and indicators, as described hereinafter. A Setting LED (light emitting diode) 48 is shown to be provided to indicate the preselected pressure that is to be applied to the chambers 32A, 32C and 32D, of the sleeves. A cycle monitor 50 is also preferably provided to continuously display the status of the controller's compression sequence. The cycle monitor 50 consists of four back lit panels, which when lighted read: ANKLE, CALF, THIGH and VENT. These represent the four major divisions of one complete cycle. During operation, the ANKLE, CALF, THIGH and VENT lights will light, one at a time, to indicate each of the major cycle divisions in turn. In addition, a ten-segment bar graph 52 is also shown to be provided. Each of the ten segments of the bar represents ten percent of a major cycle division and will light in sequence to indicate how much of a major cycle division is complete. The preferred embodiment of this invention will further include a Run LED 54 which indicates that the actual pressure is within 2mmHg of the set pressure.

After start-up, the setting LED 48 will set itself at 45mmHg and display as the set pressure. The setting LED 48 will light indicate that the microprocessor 38 is in the process of adjusting the actual pressure being supplied by the compressor 16. Within four cycles, the setting LED 48 will turn off and the Run LED 54 will come on, indicating that the actual pressure is within 3mmHg of the set pressure. The microprocessor 38 will continue to operate to make small adjustments in order to more perfectly match the set pressure.

The pressure generating device microprocessor 38 controls pressure to the sleeves by automatic pressure adjustment and not only sets the pressure automatically, but maintains the set pressure no matter how the patient moves or changes position.

With the advent of the present inventions automatic pressure adjustment, manual control is not required to adjust the pressure to the chambers during the pressure cycle, therefore, all aspects of manual control have been removed.

The automatic adjustment feature of the present invention provides a significant advance -

ment and a tremendous achievement over the prior art, therefore an advantage over all prior art. Because the present invention automatically adjusts the pressure to pressure chambers in a sleeve, the requirement to have someone constantly watch over a pressure monitor to see the rise in pressure, and then to have them continue to monitor the pressure to make sure the pressure does not exceed a preselected pressure or to make sure that the chambers have not been depressurized during the pressure cycle because of over pressurizing the chambers, has been eliminated. The nurse can start the pressure generating device, which has a preselected pressure and go on to other duties. The controller will monitor the pressure being supplied to the pressure chambers in the sleeve and will automatically adjust the pressure until the required pressure is arrived at. The controller will then continue to monitor the pressure provided throughout a pressure cycle and maintain the preselected pressure without having to manually make adjustments. The time saved by not requiring constant monitoring is substantial and makes it economically sound for use in hospitals or other health care facilities.

The present invention, even though automatically adjusting the pressure delivered to pressure chambers, also has a means, as does prior art, to depressurize the pressure chambers in the sleeves, either when the last pressure cycle has terminated, as suggested in an earlier paragraph, or in case of an involuntary shut down or overload of the pressure system.

A description is given of the present invention for clarity and understanding and no limitations are to be considered other than those proposed by the specification and claims thereof.

## Claims

1. A pressure controller for automatically controlling the compressive pressure from a generating source of pressurized fluid to a flexible sleeve adapted to enclose the limb of a patient, which sleeve has at least one pressure chamber into which the pressurized fluid is to be introduced for applying compressive pressure to the limb, the controller further being characterized by the ability to automatically adjust the pressure within the pressure chamber of the sleeve substantially to maintain a preselected pressure, the pressure controller comprising:  
valve means associated with conduit means adapted to place the pressure controller in fluid communication with the source of pressurized fluid and in fluid communication with the pressure chamber of the sleeve;
2. A pressure controller as defined in Claim 1 including means for setting the desired pressure to be applied to the chamber.
3. A pressure controller as defined in Claim 1 wherein the valve means comprises a solenoid valve.
4. A pressure controller as defined in Claim 1 wherein the means responsive to the pulses of current is a linear stepper motor.
5. A pressure controller as defined in Claim 2 wherein the comparing means includes a signal converter for converting the first electrical signal to a digital electrical signal and a microprocessor for sensing the digital signal and comparing the digital signal to the preselected value provided by the setting means.
6. A pressure generating device comprising, in combination, a flexible pressurizable sleeve having at least one chamber for applying compressive pressure to a limb of a patient, the chamber being in fluid communication with a pressure controller as defined in Claim 1, whereby to receive pressurized fluid from the

controller.

7. A pressure generating device as defined in Claim 6 wherein the sleeve contains a chamber for applying compressive pressure to the ankle, a chamber for applying compressive pressure to the calf and a chamber for applying compressive pressure to the thigh of a patient, each of the chambers being in fluid communication with the pressure controller. 5

8. A pressure generating device having a source of pressurized fluid for applying compressive forces against a patient's limb through means of a flexible sleeve which encloses the limb and has at least one pressure chamber connectable with the source, and valve means connected to the source and connectable with the pressure chamber for controlling pressure to the pressure chamber, in which the improvement comprises:

- means for sensing the pressure in the pressure chamber, the pressure sensing means including a pressure transducer for generating a first electrical signal in response to the chamber pressure;
- means responsive to the first electrical signal for automatically adjusting the pressure in the pressure chamber including:

  - means for comparing the first electrical signal to a preselected value, the comparing means including a means for generating a second electrical signal;
  - means responsive to the second electrical signal for generating pulses of current;
  - means responsive to the pulses of current from the generating means for controlling a flow control valve; and
  - a flow control valve connectable between the source of pressurized fluid and the valve means, the flow control valve controlled by the means responsive to the pulses of current for automatically adjusting the chamber pressure by regulating fluid flow through the flow control valve to the valve means.

9. The pressure generating device of Claim 8 wherein the means responsible to the pulses of current is a linear stepper motor. 30

10. The pressure generating device of Claim 8 wherein the comparing means includes a signal converter for converting the first electrical signal to a digital electrical signal and a microprocessor for sensing the digital signal and comparing the digital signal to the preselected value. 35

11. The pressure generating device of claim 10 wherein the microprocessor is programmed to monitor and to adjust pressure to a preselected pressure. 40

12. The pressure generating device of Claim 1 wherein said valve means comprises at least one solenoid valve. 45

13. A flow control valve for controlling and automatically adjusting pressure in pressure sleeves comprising:

- a hollow body member having an inlet opening and a discharge opening therein, and a chamber in communication with said inlet and discharge openings;
- a means for sealing against fluid flow entering said chamber said means including a tapered plunger member for releasably seating into said inlet opening; and
- means for moving said tapered member, said moving means including a linear stepper motor for moving said tapered member in a linear motion.

14. The flow control valve of Claim 13 wherein said linear stepper motor is calibrated to move in a linear motion in increments of on the order of about 0.002 inch. 50

15. The flow control valve of Claim 14 wherein said taper of said tapered member is a compound taper. 55

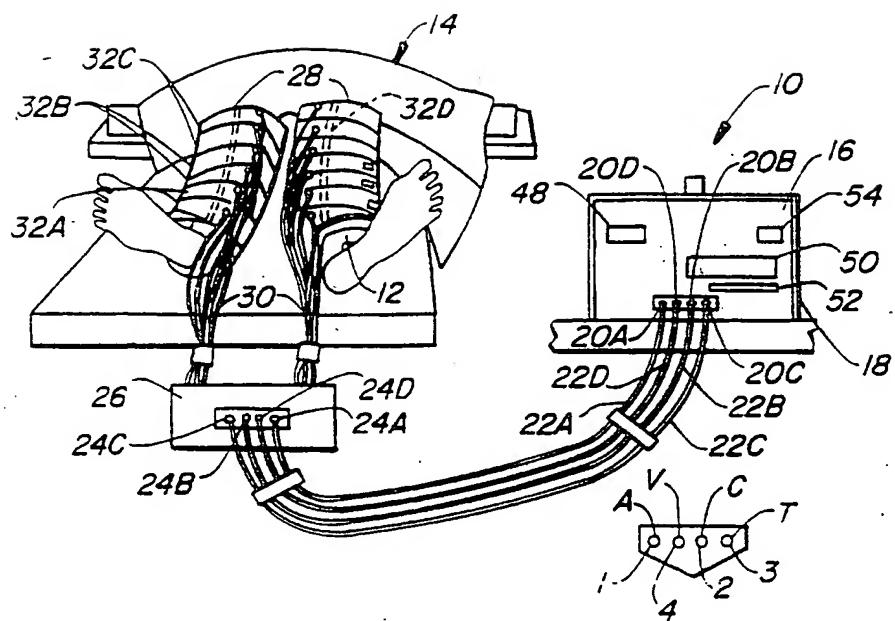


FIG. 1

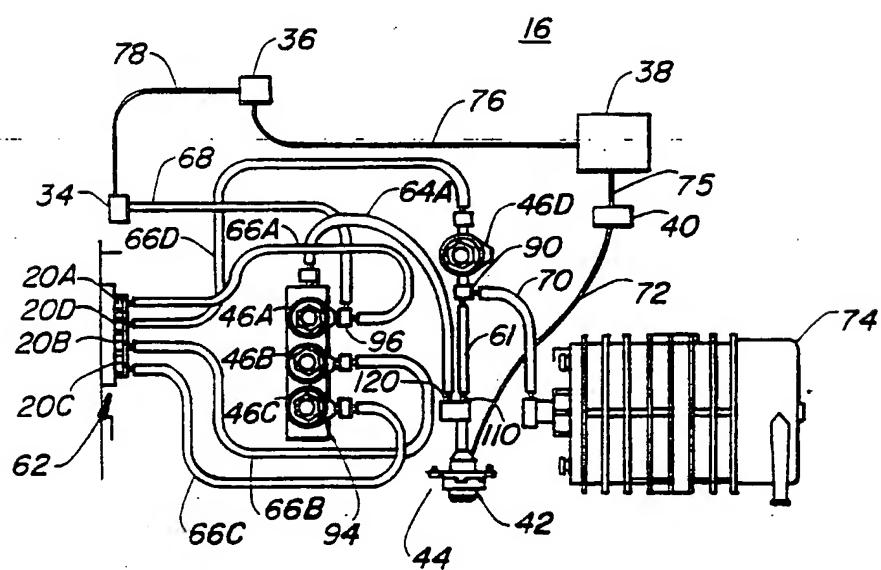


FIG. 2

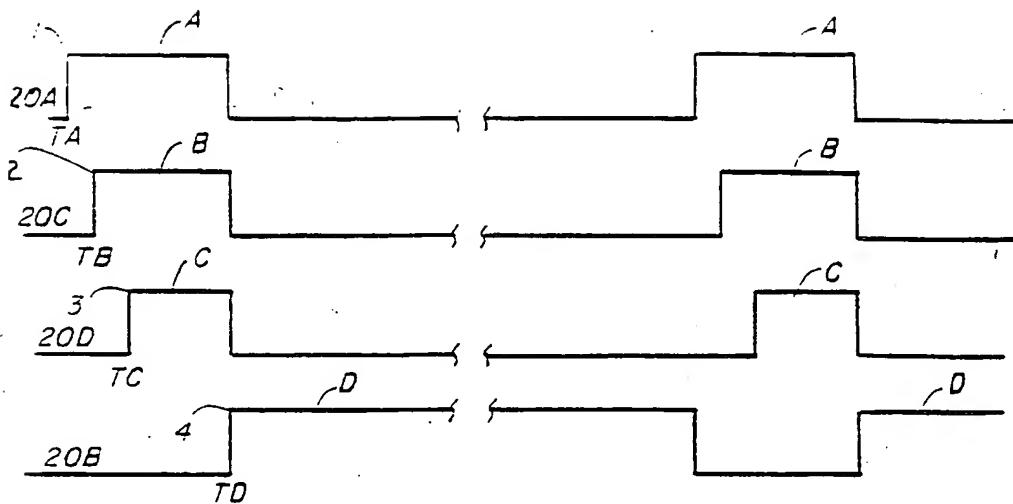


FIG. 3

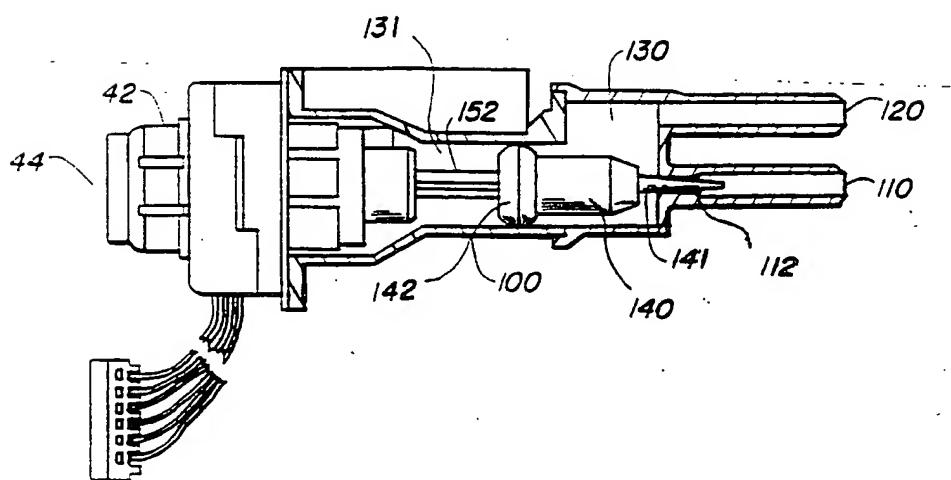


FIG. 4

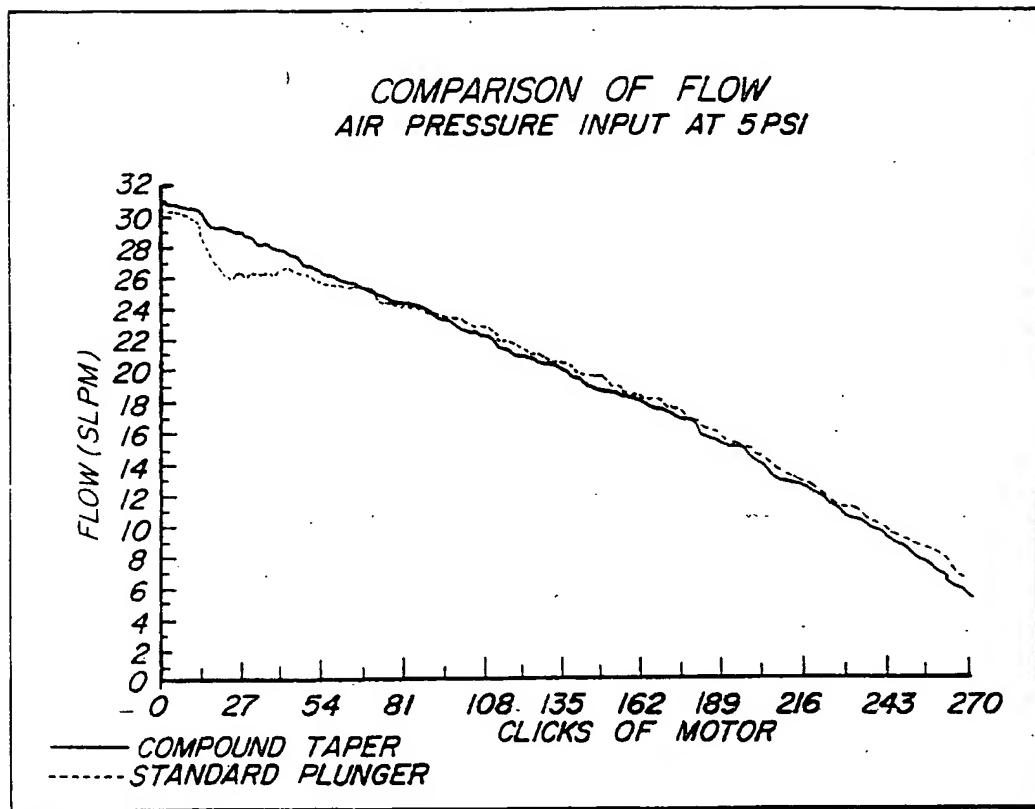


FIG. 5